Updating the Default Input Values for Exposure Variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK Model): *Estimation of Lead Bioavailability in Soil and Dust*

Peer Review Report

Prepared by:

TRW Lead Committee

Date:

December 31, 2013

TABLE OF CONTENTS

LIST OF APPENDICES

EXECUTIVE SUMMARY

The Peer Review Panel (herein referred to as Panel) reviewed a document titled *Estimation of Lead Bioavailability in Soil and Dust: Update to the Default Values for the Integrated Exposure Uptake Biokinetic Model for Lead in Children* (herein referred to as the Update Document) to address 12 charge questions regarding the information contained in the document.

The Updated Document presented a summary of the published literature and analysis of the available data regarding relative bioavailability (RBA) of lead in soil, soil-like materials and dust[1].

This Peer Review Report is intended to provide a summary of the Panel's comments and the TRW Lead Committee's revisions to the Update Document in response to the Panel's recommendations.

The Panel's review resulted in an editorial revision of the Update Document. The Panel's findings are summarized below in Section 2.2 Summary of Findings and Section 3.0 Results. The revised final Update Document may be found at http://epa.gov/superfund/lead/trw.htm.

[1]Soil samples included discrete and composite samples from a number of NPL and Superfund sites, urban and residential land, small arms firing ranges, an incinerator site, as well as two samples where soil was spiked with galena or NIST SRM lead paint. Soil samples were obtained from both U.S. and international sites.

1.0 INTRODUCTION

1.1 Background

In the IEUBK model, bioavailability (*i.e.*, *Absorption Fraction*) represents a central tendency estimate for lead that is absorbed in a child's gastrointestinal tract into the systemic circulation of blood (U.S. EPA, 1994 a,b). Soluble lead in water and food is estimated to have an absolute bioavailability (ABA) of 0.5 (50%) based on the bioavailability of soluble lead acetate (*i.e.*, the standard reference material). Lead in soil and dust; however, are estimated to have an ABA of 0.3 (30%). This value corresponds to a relative bioavailability (RBA) of 0.6 (60%; *i.e.*, $RBA = ABA_{soil\ or\ dust} / ABA_{soluble\ lead\ acetate} = 0.3/0.5$). These values were designed to provide representative estimates of lead absorption in children in the United States, but are not intended to replace representative site-specific data. Reliable, site-specific data on the bioavailability of lead in soil, dust, or other soil-like waste material can be used to improve the accuracy of lead absorption and resulting blood lead levels predicted for the sites.

The purpose of the Update Document was to review the data currently available on the lead bioavailability of soil and dust and to evaluate a potential revision to the current IEUBK model default ABA value of 30% for soil and dust. Updating the IEUBK model default value may be considered appropriate if evidence is sufficient to indicate that a Reasonable Maximum Estimate (RME) (*e.g.*, [redacted]) would be more protective for site risk assessment by accounting for variability in the RBA of lead in soil or if the RME value would encourage the use of the accurate and inexpensive assay to derive a site-specific value for RBA.

The Update Document presents an analysis of the published literature and available data regarding RBA of lead in soil. The principal objectives of the literature review and data analysis were to:

1. Identify and summarize published literature potentially relevant to estimating RBA of lead in soil. Select studies that meet predetermined quality considerations.

2. Evaluate data contained in the pertinent literature to examine whether they are adequate and sufficient to conclude that the current IEUBK model RBA for lead in soils, soil-like materials, and dusts is representative for residential scenarios at CERCLA sites and RCRA Corrective Action sites.

3. Consider use of these data, if adequate and sufficient, to recommend a quantitative central tendency or upper bound estimate of RBA for use in the IEUBK model.

This Peer Review Report was prepared to provide a summary of the Panel's comments and the TRW Lead Committee's revisions to the Update Document in response to the Panel's recommendations.

2.0 PEER REVIEW PROCESS

2.1 Peer Review Charge

The Update Document qualifies as a technical document and is eligible for an independent peer review of the content. The EPA contracted Environmental Management Support, Inc. (EMS) to conduct an independent peer review of the Update Document. EMS conducted the review of the technical document in accordance with the EPA's Science Policy Council Peer Review Handbook (U.S. EPA, 2006). Management of the review consisted of the following general activities:

- Identified areas of expertise necessary for a scientifically rigorous review.
- Identified a list of candidate expert peer reviewers.
- Evaluated the expertise of each of the candidate expert peer reviewers.
- Created a short list of candidate expert peer reviewers.
- Determined the interest and availability of the short list of candidate expert peer reviewers.
- Determined for each of the remaining list of candidate peer reviewers any potential conflict of interest or lack of impartiality, or the appearance of any potential conflict of interest or lack of impartiality; excluding candidates with either.
- Finalized a team of three expert peer reviewers.
- Developed charge questions in conjunction with the EPA for the conduct of the peer review.
- Initiated the review.
- Coordinated the peer reviewers to finalize their written reviews.

The peer review was conducted as a letter review. Each reviewer was provided a copy of the Update Document and charge questions.

In seeking candidates to serve as peer reviewers, as well as selecting the final team of reviewers, an effort was made to include individuals with expertise in one of more of the areas identified by the EPA:

- Bioavailability Assessment
- Exposure Assessment or Risk Assessment
- Biokinetics
- Pharmacokinetics
- Pharmacodynamics
- Lead Toxicokinetics or Toxicokinetics Modeling
- Physiologically-Based Pharmacokinetic Modeling

The final team of expert reviewers on the Panel consisted of the following:

- Dr. Serap Erdal, University of Illinois – Chicago School of Public Health;
- Ms. Yvette Lowney, Exponent Engineering and Scientific Consulting; and
- Dr. Paul Mushak, PB Associates.

The TRW Lead Committee thanks the Panel for providing valuable comments on the Update Document.

Efforts were made to ensure that each Panel member was allowed sufficient time to complete their review. Upon receipt by EMS, each letter review was examined and formatted for delivery to the EPA. The TRW Lead Committee's brief summary of the Panel's findings is included below as example comments received on the Update Document. The EPA's charge to the Panel and a summary of the Panel's comments are included as an appendix to this document.

2.2 Summary of Findings

- The Panel agreed that the literature review yielded an appropriate representation of currently available data. One reviewer recommended additional publications that could be included in the Update Document's analysis. The TRW Lead Committee found that these citations were not appropriate or applicable to the Update Document.

- Each reviewer recommended reorganizing and adding additional details to the Update Document to improve the clarity. Two of the three reviewers acknowledged that the scientific evidence presented was appropriate and adequate to answer questions about the current IEUBK model default value.

- The Panel agreed that clear recommendations for the IEUBK model should be made based on the discussed evidence.

3.0 RESULTS

The Panel's review comments were reviewed and considered by the TRW Lead Committee and resulted primarily in an editorial revision and a review of numerical values in the Update Document. The Panel recommended revising the Update Document's organization, but did not alter the scientific conclusions. In addition to the reorganization, the Update Document text was added to clarify the objective and findings based on the comments (see Section 3.1 below). Sections were retitled and reorganized as the following:

Peer Review Draft	Revised Draft
Overview	Overview
Analysis	Introduction
Swine Assays	In Vivo Method (Swine Assay)
Results	In Vitro Method (IVBA)
IVBA Assays	Results
Results	In Vivo Method (Swine Assay)
Limitations of Study Methodologies	In Vitro Method (IVBA)
Predicting Soil Lead at RBA Sites	Uncertainty
Implications for the IEUBK Model	Recommendations for the IEUBK Model
References	Impact on IEUBK Model Predictions
	References

The peer review panel provided a combined total of 47 comments. The majority of the comments were directed towards reorganizing the document for clarity; however, there were additional comments regarding numerical values presented in the document (see Section 3.1 below). Each comment was reviewed by the TRW Lead Committee and resolutions were incorporated into a revised draft. Additionally, the TRW Lead Committee followed up with peer reviewers on three comments to verify that the comments were understood and interpreted correctly.

Based on the peer review, the overall recommendation for the update lead bioavailability in soil and dust in the IEUBK model was: **Acceptable with revision (as outlined).**

The Appendix presents a summary of peer review questions and comments. The revised final Update Document may be found at http://epa.gov/superfund/lead/trw.htm.

3.1 Selected Comments

Representative comments were selected to demonstrate the process and overall consensus of the peer review.

COMMENT (1): The organization of the document includes the various categories appropriate for addressing its purposes. However, the document is somewhat uneven across the major headings and with respect to their logic, clarity and conciseness. The Update Document's clarity, conciseness and conclusions (or lack thereof) could be simplified/clarified in some cases and expanded in others...The draft currently lacks a section, "Recommendations", wherein specific recommendations are clearly set forth in the form of RBA/ABA figures along with discussions of any limits to exposure scenarios for those recommended values.

COMMENT (2): The "Overview" and the "Implications for the IEUBK Model" should present clear TRW Lead committee recommendations based on the discussed evidence,

or perhaps better, add a new and final section to the draft labeled "Recommendations", which would include recommendations for a default ABA/RBA for EPA's lead exposure scenarios of regulatory interest.

COMMENT (3): Missing elements include an opening section dealing with the intended purpose of the document, the intended purpose of the model, and the intended purpose of use of default values in the absence of site-specific information. A second missing element is a final section on Recommendations for use of default values and the scope of their use. Recommendations should include a general caveat that it would be difficult to use a single nationwide RBA/ABA figure for all sites and for all contamination media forms throughout the U.S.

Response to Comments 1-3: The text and tables were reorganized and additional language was added to improve the clarity of the document. Three examples of these revisions are provided below for the following sections of the Update Document: 'Overview', 'Implications for the IEUBK Model', and 'Recommendations'. In the text below black indicates original text, red indicates new text, strikeout indicates deleted text.

Overview

Since 1994, the Office of Solid Waste and Emergency Response (OSWER) has recommended the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model) as a risk assessment tool to support environmental cleanup decisions at residential sites (U.S. EPA, 1994a, b). The IEUBK model uses empirical data from numerous scientific studies of lead uptake and biokinetics, contact and intake rates of children with contaminated media, and data on the presence and behavior of environmental lead to predict a plausible distribution or geometric mean (GM) of blood lead (PbB) for a hypothetical child or population of children[2]. The relative variability of PbB concentrations around the GM is defined as the geometric standard deviation (GSD). The GSD encompasses biological and behavioral differences, measurement variability from repeat sampling, variability as a result of sample locations, and analytical variability[3]. From this distribution, the IEUBK model estimates the risk (i.e., probability) that a child's or a population of children's PbB concentration will exceed a certain level of concern as

---

[2] *The GM represents the central tendency estimate (e.g., mean, 50th percentile) of PbB concentration of children from a hypothetical population (Hogan et al., 1998). The TRW recommends that the soil contribution to dust lead be evaluated by comparing the average or arithmetic mean of soil lead concentrations from a representative area in the child's yard (U.S. EPA, 1994a). If an arithmetic mean (or average) is used, the model provides a central point estimate for risk of an elevated PbB level. By definition, a central tendency estimate is equally likely to over- or under-estimate the soil/indoor dust RBA at lead-contaminated sites. Upper confidence limits (UCLs) can be used in the IEUBK model; however, the IEUBK model results could be interpreted as a more conservative estimate of the risk of an elevated PbB level. See U.S. EPA (1994b) for further information.*

[3] *The IEUBK model uses a log-normal probability distribution to characterize this variability (U.S. EPA, 1994a). The biokinetic component of the IEUBK model output provides a central estimate of PbB concentration, which is used to provide the geometric standard deviation (GSD). The GSD encompasses biological and behavioral differences, measurement variability from repeat sampling, variability as a result of sample locations, and analytical variability. In the IEUBK model, the GSD is intended to reflect variability in PbB concentrations where different individuals are exposed to different media concentrations of lead. The recommended default value for GSD (1.6) was derived from empirical studies with young children where both blood and environmental lead concentrations were measured (White et al., 1998).*

currently established at 10 micrograms per deciliter (µg/dL) (U.S. EPA, 1994a, 1998, White et al., 1998).

The background default value for the Absorption Fraction, or ~~current IEUBK model default value for~~ absolute bioavailability (ABA) ~~of~~ for lead in soil and indoor dust in the IEUBK model is 0.3 or 30%. This value corresponds to a relative bioavailability (RBA~~, relative to water soluble lead~~) of 0.6 or 60%~~,~~ (relative to water soluble lead). The default values were originally derived from an absorption algorithm based on data from lead mass balance and feeding studies in human infants and children (U.S. EPA 1994a). ~~and is intended to be a central tendency estimate (i.e., in the middle of the range encountered at sites). However, the default central tendency estimate is equally likely to over- or under-estimate soil lead RBA when applied to a specific site. Utilization of in vivo (juvenile swine) assays and more cost-efficient in vitro bioaccessibility assays (IVBA) to provide site-specific estimates of RBA reduces uncertainty in estimates of potential human health risk at a site.~~

When reliable data are available on the bioavailability of lead in soil, dust, or other soil-like waste material at a site, this information can be used to improve the accuracy of exposure and risk calculations at that site. In application for risk assessment, bioavailability adjustments are generally applied to the concentration term. Consequently, information related to the bioavailability of a contaminant in the exposure medium may be as important as the concentration of the contaminant in that medium (although bioavailability, generally expressed as a percent, will not generally vary as much as concentration).

~~This document reviews currently available data on soil/dust lead bioavailability and evaluates uncertainties in the current default value for soil and dust bioavailability in the IEUBK model (U.S. EPA, 2008).~~

The purpose of this document is to review the data currently available on the lead bioavailability of soil and dust and to revise the default value for the soil and dust from a central tendency value of 30% to a Reasonable Maximum Estimate (RME) value of [redacted] to encourage use of the accurate and inexpensive measures of site-specific bioavailability using in an EPA-approved in vitro method (U.S. EPA, 2007 a,b; 1989). U.S. EPA performed a literature search for data on soil lead bioavailability (January 2000-August 2010), and queried U.S. EPA Regions for relevant data through August 2010. In contrast to the existing default value (which is a central estimate), the proposed soil and dust absorption fraction default is an upper percentile based on information obtained from relevant publications, as well as Superfund site assessments with in vivo (swine assays) and in vitro bioaccessibility (IVBA) data (Table 1). Using an upper percentile value as a default is expected to reduce the likelihood that sites are screened out from further evaluation by

encompassing the majority of lead species at sites (except at firing ranges). Because a relatively inexpensive IVBA method (U.S. EPA, 2007a, b) is available to characterize site-specific RBA of soil lead for most sites, we strongly recommend that site-specific estimates of soil lead bioavailability used in place of the default value to improve the accuracy of IEUBK model estimates.

Table 1. Comparison of current and proposed estimates for the Absorption Fraction variable in the IEUBK model.

Parameter	Absorption Fraction	
	Previous IEUBK Model CTE Default[a]	Proposed RME IEUBK Model Default[b]
Soil	30	[redacted]
Dust	30	[redacted]

[a]Central tendency estimates
[b]The Reasonable Maximum Exposure (RME) is based on an upper percentile estimate

This document provides the technical basis for updating the Absorption Fraction variable in the IEUBK model. The intended audience is risk assessors familiar with using the IEUBK model. For further background information on both this variable and use of the IEUBK model in Superfund lead risk assessment, refer to U.S. EPA (1994a) or the Technical Review Workgroup for Lead (TRW) website (http://epa.gov/superfund/lead/trw.htm).

Impacts on IEUBK Model Predictions

~~*Bioavailability of lead in IEUBK model simulations of blood lead concentrations is governed by the model parameter, Absorption Fraction Percent, which sets the fraction of the ingested lead dose (µg/day) that is absorbed from the gastrointestinal tract. The current IEUBK model default for this parameter is 30% for lead in soil or interior house dust, which corresponds to an RBA of 60% (relative to water soluble lead). As previously noted, this value is intended to be a central tendency estimate and, as such, would be equally likely to under- or over-estimate RBA at any particular sites, because represents the 50th percentile of all sites evaluated.*~~ *The empirical distribution of RBA values in this data set suggests that values for soil and dust lead RBA exceeding [redacted] are relatively uncommon (i.e., [redacted] of the RBA estimates exceed [redacted]). It is reasonable to expect that future RBA estimates exceeding 80% will be uncommon at similar sites of regulatory interest (e.g., remedial investigation or risk assessment). Based on these considerations, the proposed value for the Absorption Fraction variable for soil and dust is estimated to be [redacted].*

~~*Of the 23 sites (excluding firing ranges), the estimates include 12 based on swine bioassays and 11 based on IVBA assays. Distributions of RBAs for various relevant strata of the data set described in this memorandum are shown in Table 7. The sample of estimates for soils based on the combined data from IVBA assays (site means) and in vivo swine assays (excluding firing ranges and soils sieved to include particle sizes >250 µm) has a mean of 54% and a median of 60% and a 5th – 95th percentile range of 11 – 97% (n=294 soil samples, 23 sites).*~~ *This value is an upper percentile value that corresponds to an RBA of [redacted]. The selection of a default ABA value that is expected to be in the upper percentile range reduces the likelihood that sites are screened out from further evaluation when, in fact, they may present a significant health risk to young children. Table 9 presents the impact of the proposed change in the default values from 0.3 to 0.4 on geometric mean PbB estimates for children and on a hypothetical PRG estimate.*

~~*Excluding firing ranges where lead may have RBA values of 100%, soil lead RBA can be expected to have values that fall within the 5th–95th percentile range. This distribution encompasses the IEUBK model default value for soil lead RBA. The model default value of 60% corresponds to the 50th percentile of the data set.*~~ *Lead in soils and dusts from small arms firing ranges had RBA values that exceeded [redacted] (Bannon et al., 2009). Unless site-specific RBA information is available from a validated assay, the TRW recommends a default RBA of 1.0 (100%) be used in cases where site history indicates that the site was a firing range.*

Added new section: 'Recommendations for the IEUBK Model'

Based on this analysis, [redacted] is recommended as the updated value for the Absorption Fraction for soil and dust variable (Figure 1). This value corresponds to an RBA of [redacted], and is expected to be in the upper percentile range reduces the likelihood that sites are screened out from further evaluation when, in fact, they may present a significant health risk to young children. The empirical distribution of RBA values in this data set suggest that values for soil lead RBA exceeding [redacted] are relatively uncommon (i.e., [redacted] of the RBA estimates exceed [redacted]). It is reasonable to expect that future RBA estimates exceeding [redacted] will be uncommon at similar sites of regulatory interest (e.g., remedial investigation or risk assessment). Unless site-specific RBA information is available from a validated assay, the TRW recommends a default RBA of 1.0 (100%) be used in cases where site history indicates that the site was a firing range. However, for all other sites the TRW does not recommend changing this value unless site-specific information is available that meet the Data Quality Objectives of the site.

The TRW recommends that all lead-contaminated Superfund Sites include representative site-specific bioavailability using the validated IVBA test for

estimating soil lead RBA at the site (U.S. EPA, 2008)[4]. The TRW also recommends that a central tendency estimate from representative site-specific IVBA analyses be used as the input to the IEUBK model for all decision units within a site. Using a central tendency estimate for calculation of risk or a soil cleanup goal is consistent with using central tendency values as inputs to the IEUBK model (White et al., 1998).

COMMENT (4): The Results paragraph at the top of page 3 says the "mean of RBA estimates from 31 soils" is 46 percent, but this text refers to Table 2, which list a mean RBA of 54%. Many of the other values discussed in this Results paragraph are not included in the table, so it is hard to confirm the values.

Response: The values that were discussed in the text and in tables were reviewed for accuracy. Additional text was added to clarify pointers between the text and tables (see example revision below). In the text below black indicates original text, red indicates new text, strikeout indicates deleted text.

Tables 3 and 4 ~~2~~presents the summary statistics for all test materials (total of 47 different test materials, collected from 29 different sites). ~~The mean of RBA estimates from~~ Analysis of 31 soils (excluding galena-enriched soil, the NIST SRM paint sample, soil from firing ranges, and soils sieved at ≤1 mm reported in Marschner et al., 2006) ~~is 46% (SD 31),~~ resulted in a median RBA estimate of ~~is 60%, and~~ with the 5th–95th percentile range is 11–97% (Table 3); the mean RBA is 54% (SD 32; Table 4).

4.0 REFERENCES

Bannon, D.I.; Drexler, J.W.; Fent, G.M.; Casteel, S.W.; Hunter, P.J.; Brattin, W.J.; Major, M.A. 2009. Evaluation of small arms range soils for metal contamination and lead bioavailability. Environ Sci Technol. Dec 15; 43(24):9071-6.

Hogan, K.; Marcus, A.; Smith, R.; White, P. 1998. Integrated exposure, uptake, biokinetic model for lead in children: Empirical comparison with epidemiologic data. Environ. Health Perspect. 106(Suppl 6): 1557–1567. Available online at: http://www.ncbi.nlm.nih.gov.

Marschner, B.; Welge, P.; Hack, A.; Wittsiepe, J.; Wilhelm, M. 2006. Comparison of soil Pb in vitro bioaccessibility and in vivo bioavailability with Pb pools from a sequential soil extraction. Environmental Science and Technology 40(8): 2812-2818.

---

[4] *The Office of Superfund Remediation and Technology Innovation has determined that a specific in vitro bioaccessibility (IVBA) assay for lead is a validated method for predicting RBA of lead in soils for use in site-specific human health risk assessment (U.S. EPA, 2007a,b, 2008, 2009). This IVBA assay is less expensive than and less time consuming than in vivo bioavailability bioassays that have been used to estimate soil lead RBA. As a result, this IVBA assay can be used to systematically characterize soil lead RBA at sites (i.e., multiple samples per site) to reduce uncertainty in site-specific risk assessments and cleanup goals.*

U.S. Environmental Protection Agency (U.S. EPA). 1989. Review of the National Ambient Air Quality Standard for Lead: Exposure Analysis Methodology and Validation. EPA 450/2-89-011. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. June 1989.

U.S. Environmental Protection Agency (U.S. EPA). 1994a. Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children. United States Environmental Protection Agency, Office of Emergency and Remedial Response. Publication Number 9285.7-15-1. EPA/540/R-93/081.

U.S. Environmental Protection Agency (U.S. EPA). 1994b. Validation Strategy for the Integrated Exposure Uptake Biokinetic Model for Lead in Children [EPA 9285.7-21]

U.S. Environmental Protection Agency (U.S. EPA). 1998. Short Sheet: IEUBK Model Mass Fraction of Soil in Indoor Dust (M_{SD}) Variable. U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response: Washington, DC. EPA #540-F-00-008, OSWER #9285.7-34. June. Available online at: http://epa.gov/superfund/lead/products/ssmsdcol.pdf

U.S. Environmental Protection Agency (U.S. EPA). 2006, Science Policy Council Peer Review Handbook, Third Edition, June 2006, http://www.epa.gov/peerreview

U.S. Environmental Protection Agency (U.S. EPA). 2007a. Estimation of Relative Bioavailability of Lead in Soil and Soil-like Materials Using In Vivo and In Vitro methods. OSWER 9285.7-77. May 2007. Available online at: http://www.epa.gov

U.S. Environmental Protection Agency (U.S. EPA). Guidance for Evaluating the Oral Bioavailability of Metals in Soils for Use in Human Health Risk Assessment. Transmittal Memo from James E. Woolford to the Regions, dated July 3, 2007. Available online at: http://www.epa.gov

U.S. Environmental Protection Agency (U.S. EPA). 2008. Standard Operating Procedure for an In Vitro Bioaccessibility Assay for Lead in Soil. OSWER 9200.1-86. November 2008. Available online at: http://www.epa.gov

U.S. Environmental Protection Agency (U.S. EPA). 2009. Validation assessment of *in vitro* lead bioaccessibility assay for predicting relative biavailability of Lead in Soils and soil-like materials at superfund sites. OSWER 9200.3-51. Washington D.C. Available online at: http://www.epa.gov

White, P. D.; Van Leeuwen, P.; Davis, B. D.; Maddaloni, M.; Hogan, K.A., Marcus, A.H.; Elias, R.W. 1998. The conceptual structure of the integrated exposure uptake biokinetic model for lead in children. Environ Health Perspect 106 Suppl 6: 1513-1530. Available online at: http://ehpnet1.niehs.nih.gov

Appendix – Peer Review Comments

CHARGE QUESTIONS to REVIEWERS

for Peer Review of

"Updating the Default Input Values for Exposure Variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK Model), *Estimation of Lead Bioavailability in Soil and Dust*"

August 2012

Peer Review Charge for U.S. Environmental Protection Agency (EPA). Updating the Default Input Values for Exposure Variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK Model), *Estimation of Lead Bioavailability in Soil and Dust.*

EPA is seeking external peer review of the scientific basis supporting the update of several exposure variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model). The IEUBK model was developed to evaluate exposure of children (0-84 months) to lead and is used to assess risk and support environmental cleanup decisions at current or potential Superfund sites. The IEUBK model is maintained by U.S. EPA's Technical Review Workgroup Lead Committee (TRW).

The TRW Lead Committee has identified recent data that provide a more scientifically sound basis to develop nationally-representative, age-group specific default values for intake rates of lead in children. Given the available data, the TRW Lead Committee recommends updating the IEUBK model default values for the bioavailability of lead in soil and dust, water lead concentration in the United States, as well as water consumption, dietary consumption, and ventilation rates in children in the United States.

The current draft recommendations include updates to the bioavailability of lead in soil and dust, national drinking water lead concentration, as well as age-specific water, air, and food intake values. Because site-specific information is generally preferred to default values for exposure variables in the IEUBK model, it is anticipated that some of these defaults may be replaced with site-specific information. The goal of this review is to ensure that default values for exposure variables in the IEUBK model are scientifically sound and representative of reasonably current lead exposure in the United States.

Expertise Required
Peer reviewers should have an advanced degree and/or experience in toxicology, mathematics, statistics, agricultural studies, environmental health, environmental science, or environmental engineering. EPA is seeking peer reviewers with expertise in (1) bioavailability assessment; (2) lead toxicokinetics and toxicokinetics modeling; (3) either exposure assessment or risk assessment. Familiarity with the IEUBK model is beneficial. No more than one candidate peer reviewer will be selected from the same agency, consulting firm, or university.

Peer Review Charge Questions
As a peer reviewer, you are asked to assess the adequacy of this document to provide a clear and concise explanation of the scientific issues regarding the evaluation of and recommendation for updating the IEUBK model. Please comment on the use of the approaches and methodologies to derive default values presented in the following technical document: *Estimation of Lead Bioavailability in Soil and Dust*.

In evaluating the technical document: *Estimation of Lead Bioavailability in Soil and Dust*, please respond to the charge questions below. If changes are to be made, please provide the technical basis for the proposed.

Section 1: General Charge Questions

1.1 QUESTION: Is the organization of the document appropriate and is the document logical, clear and concise? Has EPA clearly synthesized the scientific evidence for the updated IEUBK model input values?

COMMENT: The reviewers generally agreed that the Update Document was successful at presenting the available data, and that the published literature used by the authors was appropriate. However, as noted by each reviewer, the Update Document needs to be reorganized for clarity and the recommendations for the IEUBK model should be stated.

1.2 QUESTION: Does the evidence presented support implementing the revisions to IEUBK model as default values for the US?

COMMENT: The reviewers agreed that the Update Document was successful at presenting the available data, and that the published literature used by the authors was appropriate. However, the reviewers agreed that the evidence does not support the use of a single ABA/RBA default, regardless of site history. Furthermore, the reviewers recommended that the evidence supports site-specific bioavailability testing for soils and dusts. Further detail on conditions that affect bioavailability was requested by one of the reviewers.

1.3 QUESTION: What are the strengths and weaknesses of approaches and methods employed given the available data?

COMMENT – Strengths: The reviewers agreed that the approaches and methods used and the comprehensive nature of the literature review provided a reliable estimation of ABA/RBA values for soil, soil-like materials, and dust (at Superfund Sites and firing ranges which resemble the sites used in this analysis).

COMMENT – Weaknesses: The reviewers noted that the Update Document does not provide a compelling synthesis of the information for drawing conclusions for nationally-representative values for use in the IEUBK model (i.e., site-specific information should be collected). Each reviewer also agreed that the document also should be reorganized for clarity and additional text should be added regarding the purpose of the IEUBK model and how the default ABA/RBA values were derived. Recommendations should also be clarified.

1.4 **QUESTION: Given the data available, what additional technical considerations can you recommend in the derivation of default values? Is EPA using appropriate models, datasets and assumptions on which to base a scientifically credible decision?**

COMMENT: Each of the reviewers agreed that database used for this analysis was appropriate; however, two of three commented that the recommendations, implications for the IEUBK model were not well articulated. These reviewers suggested that the Update Document be reorganized for clarity.

1.5 QUESTION: Are you aware of any other significant data/studies that are relevant and should be included or referenced in this document? Please identify any additional studies that should be considered in the assessment of the IEUBK model values.

COMMENT: One of the three reviewers provided three publications for inclusion:

Munir Hussain Zia, Eton E. Codling, Kirk G. Scheckel, Rufus L. Chaney. In vitro and in vivo approaches for the measurement of oral bioavailability of lead (Pb) in contaminated soils: A review. Environmental Pollution, Volume 159, Issue 10, October 2011, Pages 2320-232.

Zia, M.H., Codling, E.E., Scheckel, K.G., Chaney, R.L. Fractional bio-accessibility: a new tool with revised recommendations for lead (Pb) risk assessment for urban garden soils and superfund sites. Environmental Science and Technology, submitted for publication.

Lu, Y., Yin,W., Huang, L., Zhang, G., Zhao, Y., 2011. Assessment of bioaccessibility and exposure risk of arsenic and lead in urban soils of Guangzhou City, China. Environmental and Geochemical Health Volume 33, Pages 93-102.

Section 2. Specific Charge Questions

The current IEUBK model default value for relative bioavailability (RBA) is 60% (U.S. EPA, 1994). This value is intended to be a central tendency estimate that was derived from the evaluation of historical data (U.S. EPA, 1994). Based on a recent literature review, this document emphasizes three new recommendations for further assessing bioavailability with the IEUBK model at Superfund Sites:

- Evaluations of all lead-contaminated sites should include the application of the validated IVBA test (U.S. EPA, 2008) for estimating soil lead RBA at the site;
- If a site was used as a firing range, a default relative bioavailability of 100% should be used (unless site-specific RBA information is available from a validated assay); and
- If a site has been impacted by other sources of lead contamination (e.g., lead-based paint), site-specific bioavailability information should be collected

2.1 QUESTION: Does the document present sufficient evidence to support these recommendations?

COMMENT: Each reviewer agreed that there is evidence to support the recommendations above; however, one reviewer noted that the evidence supports the current IEUBK model default ABA value (30%) in the absence of IVBA data. One reviewer noted that further data collection (under laboratory-controlled conditions) is needed. Another reviewer added that the specific recommendations were not articulated well in the Update Document.

2.2 QUESTION: Does the document provide the adequate information needed to successfully implement these recommendations into the IEUBK model? Specifically, does the document define, present, and explain the findings of the literature review accurately?

COMMENT: One reviewer noted that the specific recommendations were not articulated well in the Update Document. This reviewer also noted that the Update Document contains "flaws in transcribing numbers from the tables to the text, and includes some numbers in the text that are never presented in the tables".

2.2.1 **QUESTION: Do you consider the timeline for the literature review (January 2000-August 2010) an appropriate representation of current available data?**

COMMENT: All reviewers agreed – Yes.

2.2.2 **QUESTION: Are you aware of relevant publications that are not highlighted in this document?**

As described in Section 1.5, one reviewer provided three publications.

2.3 QUESTION: Are the differences between the in vivo and in vitro assay clearly defined? Is the rationale for using these assays in the analysis clear?

Comment: Two of the three reviewers agreed that the differences between in-vivo and in-vitro approaches were adequately described. One of these two reviewers noted that the rationale for using these assays should be expanded (e.g., rodents vs. swine). The third reviewer did not believe the differences were adequately discussed – citing a need for and consistent use of standardized terminology. This reviewer added that additional language should be added for clarity.

2.4 QUESTION: Does the document clearly define why using the upper percentile value of [redacted] is recommended over the current central tendency estimate of 60% (excluding firing ranges, galena-enriched soils, and NIST paint)? Please comment on the strengths and weaknesses of the statistics used to derive and present the results of the bioavailability studies.

COMMENT: The reviewers generally agreed that the Update Document was successful at presenting the available data, and that the published literature used by the authors was appropriate. However, they agreed that Update Document needs to be reorganized for clarity, and one reviewer added that the numbers and text should be reviewed for accuracy.

2.5 Do you have any recommendations for additional analysis of the data? Please provide any additional data, concepts, or other considerations that would provide support for the determining a validated RBA value.

COMMENT: The reviewers generally agreed that the Update Document was successful at presenting the available data, and that the published literature

used by the authors was appropriate. However, the following recommendations were made:

- *the Update Document needs to be reorganized for clarity;*
- *recommendations for the IEUBK model should be clearly stated;*
- *explanation of the scientific basis of the current default value of 30% ABA should be articulated;*
- *detail on the function of the IEUBK model, the purpose of the document, and the intended use of the default ABA/RBA value should be added;*
- *a brief discussion on evaluating ABA/RBA as a function of remediation techniques (e.g., use of phosphate amendments) should be added;*
- *a set of proposals to further research in this area in the future should be provided; and*

As described in Section 1.5, one reviewer also provided three publications for inclusion in the Update Document.

2.6 QUESTION: Are there any elements missing that should be included or other information that would strengthen the document?

COMMENT: No comments were received.

Section 3: Recommendations

Based on your reading and analysis of the information provided, please identify and submit an explanation of your overall recommendation for the variable update on water lead concentration in the IEUBK model.

1. Acceptable as is
2. Acceptable with minor revision (as indicated)
3. Acceptable with major revision (as outlined)
4. Not acceptable (under any circumstance)

COMMENTS:

- *Reviewer 1: The draft is acceptable after appropriate attention to the document's deficits as presented above.*

- *Reviewer 2: Acceptable with major revision (as outlined): As described above, the data compiled for this evaluation are comprehensive and likely support recommendations related to assumptions of the RBA of lead in soils, for application of the IEUBK model. The analysis and write-up, however, need to be reworked to substantiate any recommendations other than those currently supported by existing guidance. As it stands, the draft document is poorly organized, poorly articulated, contains redundancies and errors, and does not articulate specific recommendations with regard to how sites should be evaluated for the RBA of lead, nor how such data would be incorporated into the IEUBK model.*

- *Reviewer 3: Acceptable with minor revision (as indicated).*

Updating the Default Input Values for Exposure Variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK Model): *Estimation of Lead Exposure from Water Sources for U.S. Children: Water Consumption*

Peer Review Report

Prepared by:

TRW Lead Committee

Date:

September 30, 2013

TABLE OF CONTENTS

LIST OF APPENDICES

EXECUTIVE SUMMARY

The Peer Review Panel (herein referred to as Panel) reviewed a document titled *Updating the Default Input Values for Exposure Variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK Model), Estimation of Lead Exposure from Water Sources for U.S. Children: Water Consumption* (herein referred to as the Update Document) to address 14 charge questions regarding the information contained in the document.

The Update Document presented a summary of the published literature and an analysis of the available data regarding nationally representative water consumption rates for children in the United States.

This Peer Review Report is intended to provide a summary of the Panel's comments and the TRW Lead Committee's revisions to the Update Document in response to the Panel's recommendations.

The Panel's review resulted in an editorial revision of the Update Document. The Panel's findings are summarized below in Section 2.2 Summary of Findings and Section 3.0 Results. The revised final Update document may be found at http://epa.gov/superfund/lead/trw.htm.

1.0 INTRODUCTION

1.1 Background

The default background values for the *Water Consumption* variable in the IEUBK model represent age-specific central tendency estimates for lead intake from water in the absence of exposures at the site being assessed. The default consumption rates were derived from the water (and water-based foods) consumption values from the U.S. Department of Agriculture's 1977-78 Nationwide Food Consumption Survey (NFCS; USDA, 1984) and the Department of Health and Human Services 1976-80 National Health and Nutrition Examination Survey (NHANES; U.S. DHHS, 1983) as reported in the Exposure Factors Handbook (U.S. EPA, 1989). Of the approximately 6,300 foods obtained from the NFCS and NHANES surveys, a representative list of commonly consumed water-based foods (water, coffee, tea, reconstituted juices, and reconstituted soups) was paired with the daily water intake information from the NFCS and used to predict total water consumption in the United States (Pennington, 1983; U.S. EPA, 1989).

The purpose of the Update Document was to provide a recommendation for revising the *Water Consumption* variable in the IEUBK model using a more representative methodology for estimating water consumption, and more recent daily average water consumption rates. Updating the IEUBK model default values may be considered appropriate if evidence is sufficient to indicate that a newer, more representative data and methodologies for calculating water consumption rates are available that would be more protective for site risk assessment.

The Update Document presents an analysis of the available data regarding childhood water consumption. The principal objectives of the review and data analysis were to:

1. Identify published literature potentially relevant to estimating water consumption rates in children. Select studies that meet predetermined quality considerations.

2. Evaluate data contained in the pertinent national databases to examine whether they are adequate and sufficient to conclude that the current IEUBK model default values for water consumption are representative (or not) for residential scenarios at Superfund sites.

3. Consider use of these data, if adequate and sufficient, to recommend quantitative central tendency estimates for water consumption for use in the IEUBK model.

This Peer Review Report was prepared to provide a summary of the Panel's comments and the TRW Lead Committee's revisions to the Update Document in response to the Panel's recommendations.

2.0 PEER REVIEW PROCESS

2.1 Peer Review Charge

The Update Document qualifies as a technical document and is eligible for an independent peer review of the content. U.S. EPA contracted Environmental Management Support, Inc. (EMS) to conduct an independent peer review of the Update Document. EMS conducted the review of the technical document in accordance with the U.S. EPA's Science Policy Council

Peer Review Handbook (U.S. EPA, 2006). Management of the review consisted of the following general activities:

- Identified areas of expertise necessary for a scientifically rigorous review.
- Identified a list of candidate expert peer reviewers.
- Evaluated the expertise of each of the candidate expert peer reviewers.
- Created a short list of candidate expert peer reviewers.
- Determined the interest and availability of the short list of candidate expert peer reviewers.
- Determined for each of the remaining list of candidate peer reviewers any potential conflict of interest or lack of impartiality, or the appearance of any potential conflict of interest or lack of impartiality; excluding candidates with either.
- Finalized a team of three expert peer reviewers.
- Developed charge questions in conjunction with U.S. EPA for the conduct of the peer review.
- Initiated the review.
- Coordinated the peer reviewers to finalize their written reviews.

The peer review was conducted as a letter review. Each reviewer was provided a copy of the Update Document and charge questions.

In seeking candidates to serve as peer reviewers, as well as selecting the final team of reviewers, an effort was made to include individuals with expertise in one of more of the areas identified by U.S. EPA:

- Water Consumption
- Lead Toxicokinetics and Toxicokinetics Modeling
- Risk Assessment or Exposure Assessment
- Toxicology
- Mathematics
- Environmental Health, Science, or Environmental Engineering

The final team of expert reviewers on the Panel consisted of the following:

- Dr. Serap Erdal, University of Illinois – Chicago School of Public Health;
- Dr. John Meeker, University of Michigan School of Public Health; and
- Dr. Paul Mushak, PB Associates.

The TRW Lead Committee thanks the Panel for providing valuable comments on the Update Document.

Efforts were made to ensure that each Panel member was allowed sufficient time to complete their review. Upon receipt by EMS, each letter review was examined and formatted for delivery to U.S. EPA. A brief summary of the Panel's findings is included in Section 3.1. U.S. EPA's charge to the Panel and a summary of the Panel's findings is included below. A summary of the Panel's comments are included as an appendix to this document.

2.2 Summary of Findings

- The Panel agreed that the CSFII database outlined in the Update Document was appropriate; however, the Panel agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support using this database over the 2003-04 and 2005-06 NHANES WWEIA database.

- The Panel also agreed that the Update Document needs to provide additional information to support using linear interpolation to estimate water consumption by age.

3.0 RESULTS

The Panel's review comments were reviewed and considered by the TRW Lead Committee and resulted primarily in an editorial revision and overall reorganization of the data presented in the Update Document. The Panel recommended revising the Update Document's organization, but did not alter the scientific methodologies, including the database used (Section 3.1). In addition to the reorganization, text was added to the Update Document to clarify the objective and findings based on the comments received from the Panel. Sections were retitled and reorganized as the following:

Peer Review Draft	Revised Draft
Overview	Overview
Analysis	Introduction
References	Technical Analysis
	Uncertainty
	Results
	Recommendations for the IEUBK Model
	Impact on the IEUBK Model Predictions
	References

The Panel provided a combined total of 50 comments. The majority of the comments were directed towards reorganizing the document for clarity. Each comment was reviewed by the TRW Lead Committee and resolutions were incorporated into a revised draft.

Based on the review of the Update Document, the Panel's overall recommendation for the update of the *Water Consumption* variable in the IEUBK model was: **Acceptable with minor revision (as indicated).**

The Appendix presents a summary of peer review questions and comments.

3.1 Selected Comments

Representative comments were selected to demonstrate the process and overall consensus of the peer review. In the text below black indicates original text, red indicates new text, and strikeout indicates deleted text.

COMMENT (1): The inclusion of more details in certain areas may help the flow of information and more clearly state the options and justification for the decision to use the selected data. For example, further background information could be included on why this was being considered, more details on the data sources being considered, how this relates to the exposure factors handbook and that process, more details on the methods used for the linear interpolation performed in Table 1 and, finally, a conclusion paragraph.

COMMENT (2): The draft does contain much of the data needed for an analysis of default values for children's water Pb consumption rates in the IEUBK model. The analysis needs completeness and clarity. As I recommended with the other drafts, the draft can be expanded with added sections. Such added headings could include "Results" or "Analysis and Results", "Implications" for the IEUBK model, "Limitations of the Methodologies", "Scope of the Methodologies"... Use of more sections with their discussions would help. The draft could benefit with some rearrangement of the information and the data sets.

Response to Comments 1 & 2: The Update Document was reorganized for clarity and additional sections and text were added describing how the water consumption values were calculated. Specifically, an 'Introduction', 'Technical Analysis', 'Uncertainty', 'Results', 'Recommendations for the IEUBK Model' and 'Impacts on the IEUBK Model Predictions' sections were added.

COMMENT (3): Table 4, providing sample size comparisons of the Kahn and Stralka, 2009 analyses with the NHANES/WWEIA 2003-06 data set, appears out of nowhere and needs discussion in the text along with the logic for its inclusion. While the sampling sizes are greater with the CSFII versus the NHANES data sets, sample size beyond a minimum count requirement is but one criterion for judging the overall validity of data. Did the authors analyze the NHANES 2003-06 dataset beyond simply comparing sample sizes? A data set with smaller sample size, but a representative size nonetheless, may have other strengths that justify its inclusion for analyses. Inclusion of Table 4 and the associated short single paragraph piques the reader's interest as to what values arise from the NHANES data. In any case, more needs to be said about the NHANES 2003-06 dataset, including why analyses were not at least attempted with the NHANES data.

COMMENT (4): As to weaknesses in the overall approach, the authors should note why there were no analyses of the NHANES 2003-06 data set, a data set that was gathered later than the 1994-1996, 1998 CSFII sets. The later NHANES set would, as recognized by the authors, account for more changes in water consumption patterns in the U.S. The authors note that the NHANES data would better capture the increase in bottled water use.

COMMENT (5): Particularly, the analysis does not fully take advantage of the NHANES 2003-2006 data. It does list at the end of the document the differences between CSFII and NHANES data sets but it omits any data analysis using the NHANES data set.

Response to Comments 3, 4 & 5: Additional text was added to the Update Document to explain using the 1994-96 and 1998 CSFII databases instead of the 2003-04 and 2005-06 NHANES WWEIA data.

Revised text:

TECHNICAL ANALYSIS

Information on dietary intakes, including water consumption, was extracted from the NHANES WWEIA data files (U.S. CDC, 2010a,b). Data from the two most recent 2-year cycles (2003-04 & 2005-06)[1] were used, in accordance with U.S. CDC recommendations (U.S. CDC, 2006). A comparison of the sample sizes available from the 2003-04 and 2005-06 WWEIA and the 1994-96 & 1998 CSFII survey data are provided in Table 4.

~~The TRW Lead Committee also compared the CSFII 1994-96, 1998 data set (USDA, 2000) to the more recent National Health and Nutrition Examination Survey [(NHANES 2003-06); dietary intake taken data from *What We Eat in America* (WWEIA)]. The major differences were: (1) both studies were designed to estimate dietary intake for the non-institutionalized U.S. population[2]; (2) sample sizes reported by Kahn and Stralka (2009) show the CSFII 1994-96, 1998 sample sizes are at least twice the sample size available in the NHANES WWEIA 2003-06 data (Table 4); and (3) bottled water consumption has increased since the time of the CSFII 1994-96, 1998 survey.~~

Table 4. Sample size comparison (number of participants) by age range for the CSFII as compared to NHANES (WWEIA) 2003-2004 and 2005-2006. -The number of survey participants are shown in parentheses.

CSFII 1994-96 & 1998[a]	NHANES (WWEIA) 2003-2006 (IEUBK Age groups)[b]
< 1 (58) ~~0 < 11 months (1266)~~	0 < 12 months (820)
1 < 3 (178)	
3 < 6 (363)	
6 < 12 (667)	
12 < 234 (1017)	12 < 24 months (559)
24 < 356 (1051)	24 < 36 months (510)
36 < 7+2 (4350)	36 < 48 months (308)
	48 < 60 months (363)
	60 < 72 months (304)
72 < 132 (1659)	72 < 84 months (331)
	≥84 months (13,299)

[a] Source: Kahn and Stralka, 2009; Table 1. Consumers only, ~~All Water Sources.~~Total Water.
[b] Sample sizes correspond to individuals with two days of complete and reliable dietary recall data (CDC, 2010a, b).

New Sections Added:

UNCERTAINTY

Based on the evaluation of the 2003-2004 and 2005-2006 NHANES WWEIA data (US CDC, 2010 a,b), the biggest difference between the types and amount of water consumed currently and the types and amount of water consumed at the time of the CSFII 1994-96 and 1998 surveys may be found in bottled water. However, if the concern is exposure to lead in drinking water derived from the site, bottled water may not be a concern (i.e., the community water consumption rates recommended in this report do not include bottled water).

[1] The 2003-04 & 2005-06 dietary data were the most recent available data at the time this research was initiated.
[2] The CSFII 1994-96, 1998 does not identify subpopulations (income level, ethnicity), while the NHANES survey does

RECOMMENDATIONS FOR THE IEUBK MODEL
The TRW elected to use the consumption rate estimates by Kahn And Stralka (2009) over the 2003-04 and 2005-06 NHANES WWEIA because the 1994-1996 and 1998 CSFII database: a) included more survey participants, b) received a high level of peer review (U.S. EPA, 2011, 2010), and c) the sources of uncertainty were minimal (U.S. EPA, 2009).

COMMENT (6): Adding a discussion of the overall end results of the updated values and potential consequences of making these updates to the water consumption estimates vs. not making these updates may further support the decision for the new values. For example, the updated consumption values would be slightly higher for a number of age groups but lower for ages 12 months to 36 months. Are these differences expected to result in large changes to the downstream uses of these data for risk assessment and decision-making?

Response to Comment 6: With the reorganization of the Update Document, an additional section (including a summary table) was added to illustrate the impact of the recommended changes on the IEUBK model predictions.

New Section Added:
IMPACT ON THE IEUBK MODEL PREDICTIONS
Using current IEUBK model defaults for all other parameters while implementing the recommended water consumption rates will increase the GM PbB for children (0-7 years of age) from 2.730 µg Pb/dL to [redacted] µg/dL. Table 5 presents the updated estimates. As shown in Table 5, the recommended changes do not have a significant impact on the probability of the geometric mean exceeding 10 µg/dL nor do they impact PRGs in the soil lead concentration range (in the interest for OSRTI).

Table 5. Effects of changing the water consumption variable in the IEUBK model

Source	Age Range (months)							GM	P_{10}	PRG for 5% NTE 5 µg/dL	PRG for 5% NTE 10 µg/dL
	0 < 12	12 < 24	24 < 36	36 < 48	48 < 60	60 < 72	72 < 84				
IEUBK Model Default Value[a]											
Consumption Rate (L/day)	0.2	0.5	0.52	0.53	0.55	0.58	0.59	2.730	0.287	153	418
Lead Uptake from Water (µg/day)	0.375	0.929	0.976	1.004	1.059	1.123	1.146				
Calculated Total Lead Uptake (µg/day)	5.586	8.368	8.593	8.651	7.045	6.720	6.592				
Calculated Blood Lead Concentration (µg/dL)	3.0	3.5	3.2	3.0	2.5	2.1	1.9				
Recommended IEUBK Model Default Value[b]											
Consumption Rate (L/day)	[redacted]							[redacted]			
Lead Uptake from Water (µg/day)											
Calculated Total Lead Uptake (µg/day)											
Calculated Blood Lead Concentration (µg/dL)											

GM: Geometric mean blood lead concentration (µg/dL) for 0-84 month age range; NTE: Not to Exceed; P10: Probability of the predicted GM blood lead concentration ≤ 10 µg/dL; PRG: preliminary remediation goal; NTE: not to exceed

[a] *IEUBK Model (v. 1.1, build 11)*

[b] *Kahn and Stralka, 2009; all water sources, consumers only*

4.0 REFERENCES

Kahn, H., Stralka, K. 2009. Estimated daily average per capita water ingestion by child and adult age categories based on USDA's 1994-96 and 1998 continuing survey of food intakes (CSFII). J Expo Sci Environ Epidemiol. 19(4):396-404. Epub 2008 May 14.

Pennington, J. A. T. 1983. Revision of the total diet study food list and diets. J. Am. Dietetic Assoc. 82(2): 166-173.

U.S. Centers for Disease Control and Prevention (U.S. CDC). 2006. Analytic and Reporting Guidelines. The National Health and Nutrition Examination Survey (NHANES). National Center for Health Statistics. Last Update: December, 2005. Last Correction, September, 2006.

U.S. Centers for Disease Control and Prevention (U.S. CDC). 2010a. National Health and Nutrition Examination Survey. 2003-2004 Examination, Dietary, and Demographics Files. Retrieved October 4, 2010 from http://www.cdc.gov/nchs/nhanes/nhanes2003-2004.

U.S. Centers for Disease Control and Prevention (U.S. CDC). 2010b. National Health and Nutrition Examination Survey. 2005-2006 Examination, Dietary and Files. Retrieved October 4, 2010 from http://www.cdc.gov/nchs/nhanes/nhanes2005-2006.

U.S. Department of Agriculture, Agricultural Research Service (USDA). 1984. Nutrient intakes: Individuals in the United States, year 1977-1978, NCFS 1977-1978. Washington, D.C.: U.S. Dept. of Agriculture, Human Nutrition Information Service; Report No. I-2; 1984.

U.S. Department of Agriculture, Agricultural Research Service (USDA). 1995. Food and nutrient intakes by individuals in the United States, 1 day, 1989-1991. Washington, D.C.: U.S. Dept. of Agriculture, Human Nutrition Information Service; NFS Report No. 9-12.

U.S. Department of Agriculture, Agricultural Research Service (USDA). 2000.1994–1996, and 1998 Continuing Survey of Food Intakes by Individuals and 1994–1996 Diet and Health Knowledge Survey, CD–ROM, accession number PB98–500457.

U.S. Department of Health and Human Services (U.S. DHHS). 1983. Dietary intakes source data: United States. 1976-1980. Hyattsville, MD: Department of Health and Human Services, National Center for Health Statistics; DHHS Publication No. (PHS) 83-1681.

U.S. Environmental Protection Agency (US EPA). 1989. Exposure Factors Handbook. National Center for Environmental Assessment, Office of Research and Development.

U.S. Environmental Protection Agency (U.S. EPA). 2006. Guidance on Systematic Planning Using the Data Quality Objectives Process. EPA/240/B-06/001. Available online at: www.epa.gov

U.S. Environmental Protection Agency (US EPA). 2010. SAB REVIEW DRAFT: Approach for developing lead dust hazard standards for residences. December 6-7, 2010.

U.S. Environmental Protection Agency (US EPA). 2011. Exposure Factors Handbook (Final). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-09/052F, 2011.

Appendix – Peer Review Comments

CHARGE QUESTIONS to REVIEWERS

for Peer Review of

"Updating the Default Input Values for Exposure Variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK Model), *Estimation of Lead Exposure from Water Sources for U.S. Children: Water Consumption*"

December 2012

U.S. Environmental Protection Agency (U.S. EPA). Updating the Default Input Values for Exposure Variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK Model), *Estimation of Lead Exposure from Water Sources for U.S. Children: Water Consumption*.

Background:
U.S. EPA is seeking external peer review of the scientific basis supporting the update of several exposure variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model). The IEUBK model was developed to evaluate exposure of children (0-84 months) to lead and is used to assess risk and support environmental cleanup decisions at current or potential Superfund sites. The IEUBK model is maintained by U.S. EPA's Technical Review Workgroup (TRW) Lead Committee.

The TRW Lead Committee has identified recent data that provide a more scientifically sound basis to develop nationally-representative, age-group specific default values for intake rates of lead in children. Given the available data, the TRW Lead Committee recommends updating the IEUBK model default values for the bioavailability of lead in soil and dust, water lead concentration in the United States, as well as water consumption, dietary consumption, and ventilation rates in children in the United States.

The current draft recommendations include updates to the bioavailability of lead in soil and dust, national drinking water lead concentration, as well as age-specific water, air, and food intake values. Because site-specific information is generally preferred to default values for exposure variables in the IEUBK model, it is anticipated that some of these defaults may be replaced with site-specific information. The goal of this review is to ensure that default values for exposure variables in the IEUBK model are scientifically sound and representative of reasonably current lead exposure in the United States.

Expertise Required:
Peer reviewers should have an advanced degree and/or experience in toxicology, mathematics, environmental health, environmental science, or environmental engineering. EPA is seeking peer reviewers with expertise in (1) water consumption; (2) lead toxicokinetics and toxicokinetics modeling; (3) risk assessment or exposure assessment. Familiarity with the IEUBK model is beneficial. No more than one candidate peer reviewer will be selected from the same agency, consulting firm, or university.

Peer Review Charge Questions:
As a peer reviewer, you are asked to assess the adequacy of this document to provide a clear and concise explanation of the scientific issues regarding the evaluation of and recommendation for updating the IEUBK model. Please comment on the use of the approaches and methodologies to derive default values presented in the following technical document: *Estimation of Lead Exposure from Water Sources for U.S. Children: Water Consumption.*

In evaluating the technical document: *Estimation of Lead Exposure from Water Sources for U.S.* Children*: Water Consumption*, please respond to the charge questions below. If changes are to be made, please provide the technical basis for the proposed changes, citing any improvements, publications or literature that supports your response.

Section 1: General Charge Questions

1.1 QUESTION: Is the organization of the document appropriate and is the document logical, clear and concise? Has EPA clearly synthesized the scientific evidence for the updated IEUBK model input values?

COMMENT: The Panel agreed that the CSFII database outlined in the Update Document was appropriate; however, each reviewer agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support using this database over the 2003-04 and 2005-06 NHANES WWEIA database. The Panel also agreed that the Update Document needs to provide additional information to support using linear interpolation to estimate water consumption by age.

1.2 QUESTION: Does the evidence presented support implementing the revisions to IEUBK model as default values for the US?

COMMENT: The Panel agreed – yes, and noted that the evidence supports changing the IEUBK model default values.

1.3 QUESTION: What are the strengths and weaknesses of approaches and methods employed given the available data?

COMMENT – Strengths: The Panel agreed that using Kahn and Stralka (2009) was appropriate, and that the 1994-96 & 1998 CSFII data was robust. Furthermore, the Panel agreed with the use of total water consumption from consumers-only was the correct approach.

COMMENT – Weaknesses: The Panel noted that the Update Document does not provide sufficient information on choosing the 1994-96 & 1998 CSFII over the 2003-04 and 2005-06 NHANES WWEIA. One reviewer noted that linear interpolation may not reflect non-linear trends in child development or water consumption over time.

1.4 QUESTION: Given the data available, what additional technical considerations can you recommend in the derivation of default values? Is EPA using appropriate models, datasets and assumptions on which to base a scientifically credible decision?

COMMENT: The Panel agreed that the CSFII database outlined in the Update Document was appropriate; however, the reviewers agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support using this database over the 2003-04 and 2005-06 NHANES WWEIA database. The Panel also agreed that the Update Document needs to provide additional information to support using linear interpolation to estimate water consumption by age.

1.5 QUESTION: Are you aware of any other significant data/studies that are relevant and should be included or referenced in this document? Please identify any additional studies that should be considered in the assessment of the IEUBK model values.

COMMENT: One reviewer recommended reviewing the Exposure Factors Handbook (U.S. EPA, 2011).

Section 2. Specific Charge Questions

This document recommends replacing the current, age-specific IEUBK model default water consumption value (based on U.S. EPA, 1997) with the CSFII 1994-96 & 1998 data as analyzed by Kahn & Stralka (2009).

2.1 **QUESTION:** Kahn and Stralka (2009) derived mean and percentile estimates of age-specific, daily water consumption rates from the 1994-96 and 1998 Continuing Survey of Food Intakes by Individuals (CSFII) [as reported in USDA (2000)].

2.1.1 Do you agree with the use of the CSFII (1994-96, 1998) data to estimate water consumption vs. the most recent NHANES survey?

COMMENT: The Panel agreed that additional information was needed on how these datasets were compared before agreeing that these were appropriately chosen.

2.1.2 Are the methods and procedures set forth in Kahn and Stralka (2009) adequate to ensure that scientifically valid water consumption values are derived?

COMMENT: The Panel agreed that the method discussed in the section on Kahn and Stralka (2009) was adequate.

2.2 **QUESTION:** U.S. EPA (2009) recommends the value derived from Kahn and Stralka (2009) "Estimated direct and indirect community water ingestion; all individuals (i.e., Community water, All individuals)" be used to represent water consumption in the United States.

2.2.1 Do you agree with the document's selection to use of "All water Sources, Consumers Only" to represent water consumption?

COMMENT: The Panel agreed – yes. One reviewer added that these data are more relevant and more conservative.

2.2.2 Please comment on the selection of the overall population and the various subpopulations at risk (e.g., children, "consumers", "all individuals")

COMMENT: The Panel agreed with the selection of the subpopulations at risk was appropriate.

2.2.3 Do you agree with using linear interpolation to pair Kahn and Stralka (2009) age specific data to the IEUBK model age groups vs. time weighted averages?

COMMENT: The Panel agreed that the Update Document should provide additional information on linear interpolations.

3.0 QUESTION: Do you agree that the recommendation that the new age-specific default values are appropriate, nationally representative estimate of water consumption in the United States to use as the basis for a default value in the IEUBK model?

COMMENT: The Panel agreed that the Update Document should provide additional information on linear interpolations.

4.0 QUESTION: Do you have any recommendations for additional analysis of the data? Please provide any additional data, concepts, or other considerations that would provide support for the age-specific values.

COMMENT: The Panel agreed that the CSFII database outlined in the Update Document was appropriate; however, each reviewer agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support using this database over the 2003-04 and 2005-06 NHANES WWEIA database. The Panel also agreed that the Update Document needs to provide additional information to support using linear interpolation to estimate water consumption by age.

Section 3: Recommendations

Based on your reading and analysis of the information provided, please identify and **submit an explanation of your overall recommendation for the updating the water** consumption variable in the IEUBK model.

1. Acceptable as is
2. Acceptable with minor revision (as indicated)
3. Acceptable with major revision (as outlined)
4. Not acceptable (under any circumstance)

COMMENTS:

- *Reviewer 1: Acceptable with minor revision (as indicated). "As stated above, I believe the case for updating the consumption values as proposed could be strengthened with the addition of certain details not currently included in the document and careful consideration of the details surrounding the linear interpolation of values from Kahn and Stralka."*

- *Reviewer 2: Acceptable with minor revision (as indicated)*

- *Reviewer 3: Acceptable with minor revision (as indicated)*